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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,478	03/04/2002	Jin Jen	126881201800	1461
30089	7590	10/18/2005	EXAMINER	
GENZYME CORPORATION C/O BINGHAM MCCUTCHEN BINGHAM MCCUTCHEN, LLP SAN FRANCISCO, CA 94111			RAWLINGS, STEPHEN L	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/646,478	Applicant(s) JEN ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-30 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-11 and 14-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20041102</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed March 21, 2005 is acknowledged and has been entered. Claims 12 and 13 have been amended.
2. The amendment filed April 20, 2005 is acknowledged and has been entered.
3. The amendment filed August 5, 2005 is acknowledged and has been entered. Claim 3 has been canceled. Claims 1, 12, and 13 have been amended.
4. Claims 1, 2, and 4-30 are pending in the application. Claims 2, 4-11, and 14-30 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 7, 2004.
5. Claims 1, 12, and 13, drawn to the elected invention, are currently under prosecution.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

7. The information disclosure filed October 29, 2004 has been considered. An initialed copy is enclosed.

Oath/Declaration

8. As explained the preceding Office action mailed October 20, 2004, the declaration is defective. Accordingly, a new oath or declaration in compliance with 37

CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-dated alterations have been made. See 37 CFR § 1.52(c).

At page 6 of the amendment filed April 20, 2005 Applicant has stated that a new declaration will be provided; however, until it is provided, this issue will remain unresolved.

Grounds of Objection and Rejection Withdrawn

9. Unless specifically reiterated below, Applicant's amendment and/or arguments filed in response to the preceding Office action mailed October 20, 2004 have obviated or rendered moot the grounds of objection and rejection set forth in that Office action.

Claim Rejections Maintained

Claim Rejections - 35 USC § 102

10. The rejection of claims 1, 12, and 13 under 35 U.S.C. 102(b) as being anticipated by Mooi et al. (*Histopathology*. 1988 Sep; **13** (3): 329-337), as evidenced by Wilkinson et al. (*Science*. 1989 Nov 3; **246** (4930): 670-673), is maintained.

At pages 3 and 4 of the amendment filed March 21, 2005 and at pages 7 and 8 of the amendment filed April 20, 2005 Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

Applicant has argued that Mooi et al. does not anticipate each and every limitation of the claims, since, in particular, Mooi et al. does not explicitly teach the proto-oncogene encoding PGP9.5 is "over-expressed" in lung cancer, or that its over-expression is indicative of a neoplastic condition of lung cells.

The claims are drawn to a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of "an overexpressed proto-oncogene", namely PGP9.5 in a lung cell sample (claim 1), wherein the presence of the overexpressed proto-oncogene is determined by detecting the quantity of the protein

encoded by the gene (claim 12) or wherein the neoplastic condition of a lung cell is non-small cell lung cancer (claim 13).

As explained in the preceding Office action, Mooi et al. teaches a method for aiding in the diagnosis of a neoplastic condition of the lung comprising detecting the presence of PGP9.5 (i.e., the protein encoded by the proto-oncogene to which the claims are directed) in a lung sample. Mooi et al. teaches the presence of PGP9.5 in lung cancer samples is indicative of non-small cell lung cancer.

As evidenced by Wilkinson et al., the gene encoding PGP9.5 is only expressed in select neurons and ganglia; therefore, it is not expressed in normal lung; see page 7, section 13, paragraph 4. Accordingly, any amount of expression of the gene in lung cells, including lung cancer cells, is reasonably considered "over-expression" (i.e., a level of expression higher than normal).

Accordingly, although Mooi et al. does not expressly teach that the gene is over-expressed *per se*, because Wilkinson et al. teaches that the gene encoding PGP9.5 is not expressed in normal lung, if this proto-oncogene is expressed to any extent in lung cell cancer, it is "over-expressed".

Further addressing Applicant's argument that reference does not teach the use of PGP9.5 as a tumor cell marker, Mooi et al. expressly teaches non-small cell lung carcinomas with neuroendocrine features, including the expression of the proto-oncogene encoding PGP9.5; see, e.g., the abstract. Moreover, Mooi et al. teaches identification of neuroendocrine differentiation in lung tissue aids in the diagnostic classification of lung cancer (abstract). Therefore, contrary to Applicant's assertion, Mooi et al. does indeed teach the use of PGP9.5 as a tumor cell marker.

Applicant's remaining remarks at pages 3 and 4 of the amendment filed March 21, 2005 are acknowledged, but they do not serve to differentiate the claimed process from the process disclosed by the prior art.

At page 8 of the amendment filed April 20, 2005 Applicant has asserted that it is improper to cite Wilkinson et al. as a basis for a rejection under 35 U.S.C. § 102, as such a rejection requires that all elements of the claim be taught by a single reference.

MPEP § 2112 states:

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The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

MPEP § 2112 further states that the Examiner must provide rationale or evidence tending to show inherency:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) [...]. "To establish inherency, the extrinsic evidence must make clear the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill [...] *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) [...]

Furthermore, MPEP 2131.01 states:

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such a gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) [...] Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) [...] [T]he critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

Therefore, contrary to Applicant's assertion, Wilkinson et al. is properly cited as an evidentiary reference showing that the proto-oncogene encoding PGP9.5 is not expressed in lung cells.

As explained above, even though Mooi et al. does not teach the proto-oncogene is "over-expressed" *per se*, Mooi et al teaches all elements of the claims, since, as evidenced by Wilkinson et al., the proto-oncogene is not expressed in normal lung

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tissue and therefore any amount of expression in lung cancer is reasonably deemed "over-expression".

Thus, Applicant's arguments have been carefully considered but not found persuasive to overcome this ground of rejection.

Conclusion

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.
Examiner
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slr
October 14, 2005